Administrative Record Index
Food and Drug Administration
Citizen Petition – Docket 98P-0311/CPI
(Administrative Record Consists of All Listed Documents, and References and Attachments Cited Therein)

Petition & Comments

1. May 12, 1998 Citizen's Petition, identified as 98P-0311/CPI, from Stuart J. Land at Arnold & Porter and Nancy L. Buc at Buc & Beardsley, on behalf of their client, Wyeth-Ayerst Laboratories, Division of American Home Products

2. May 13, 1998 letter from Gloria Ortega, Dockets Management Branch, Food and Drug Administration, to Stuart J. Land, Arnold & Porter

3. May 16, 1998 letter regarding equine source of Premarin from Jeanine M. Sieler to Dr. Shalala

4. May 16, 1998 letter regarding equine source of Premarin from Susan Grant to Dr. Shalala

5. August 4, 1998 comment from Charles J. Cooper at Cooper, Carvin & Rosenthal on behalf of Duramed Pharmaceuticals, Inc., to Docket 98P-0311/CPI

6. August 5, 1998 letter from Charles J. Cooper at Cooper, Carvin & Rosenthal on behalf of Duramed Pharmaceuticals, Inc., to Docket 98P-0311/CPI

7. August 5, 1998 revised comment letter from Charles J. Cooper at Cooper, Carvin & Rosenthal on behalf of Duramed Pharmaceuticals, Inc., to to Docket 98P-0311/CPI

8. November 4, 1998 interim response letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Stuart J. Land at Arnold & Porter

9. January 7, 1999 letter from Stuart J. Land at Arnold & Porter and Nancy L. Buc at Buc & Beardsley, on behalf of their client, Wyeth-Ayerst Laboratories, Division of American Home Products to Docket 98P-0311/CPI

10. January 27, 1999 letter from Catherine Colette, Director, Women's Rights Department, American Federation of State, County, and Municipal Employees, AFSCME; Wayne Shields, President and CEO, Association of Reproductive Health Professionals (ARHP); Leslie R. Wolfe, President, Center for Women Policy Studies; Susan Wysocki, President, National Association of Nurse Practitioners in Reproductive Health; Linda F. Golodner, President, National Consumers League; Judith L. Lichtman, President, National Partnership for Women & Families; and

98P-0311 REF 1

Marcia Greenberger, Co-President, National Women's Law Center, to Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration

11. February 2, 1998 letter from Charles J. Cooper, Cooper, Carvin, & Rosenthal, as counsel to Duramed Pharmaceuticals, Inc., to Catherine Colette, Director, Women's Rights Department, American Federation of State, County, and Municipal Employees, AFSCME; Wayne Shields, President and CEO, Association of Reproductive Health Professionals (ARHP); Leslie R. Wolfe, President, Center for Women Policy Studies; Susan Wysocki, President, National Association of Nurse Practitioners in Reproductive Health; Linda F. Golodner, President, National Consumers League; Judith L. Lichtman, President, National Partnership for Women & Families; and Marcia Greenberger, Co-President, National Women's Law Center

12. February 16, 1999 letter from Catherine Colette, Director, Women's Rights Department, American Federation of State, County, and Municipal Employees, AFSCME; Wayne Shields, President and CEO, Association of Reproductive Health Professionals (ARHP); Leslie R. Wolfe, President, Center for Women Policy Studies; Susan Wysocki, President, National Association of Nurse Practitioners in Reproductive Health; Linda F. Golodner, President, National Consumers League; Judith L. Lichtman, President, National Partnership for Women & Families; and Marcia Greenberger, Co-President, National Women's Law Center, to Charles J. Cooper, Cooper, Carvin & Rosenthal

13. February 16, 1999 letter from Linda F. Golodner, National Consumers League, to Charles J. Cooper at Cooper, Carvin & Rosenthal

14. February 17, 1999 letter from Wayne Shields, President and CEO, Association of Reproductive Health Professionals (ARHP) and Susan Wysocki, President, National Association of Nurse Practitioners in Reproductive Health, to Charles J. Cooper at Cooper, Carvin & Rosenthal

15. February 19, 1999 letter from Nancy L. Buc, Buc & Beardsley, to Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration

16. February 24, 1999 letter from Robert M. Elenbaas, Pharm. D., FCCP, at the American College of Clinical Pharmacy to Docket 98P-0311/CPI

17. March 24, 1999 Response to Citizen Petition 98P-0311/CP.

Other Documents

18. May 5, 1997 memo "Approvability of a Synthetic Generic Version of Premarin" from Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Director, Office of Generic Drugs, Food and Drug Administration (references and background documents available in Docket 97-NO325)

19. June 9, 1997 letter from Yana Ruth Mille, Chief, Compendial Operations Staff, Center for Drug Evaluation and Research, to Joseph G. Valentino, J.D., Senior Vice President and General Counsel, The United States Pharmacopeial Convention, Inc.

20. November 5, 1998 Meeting Minutes between Food and Drug Administration and Representatives of Wyeth-Ayerst Laboratories, Division of American Home Products Corporation

21. November 9, 1998 letter and attachments from Justin R. Victoria, Wyeth-Ayerst Research, to Jane Axelrad, Associate Director, Center for Drug Evaluation and Research, Food and Drug Administration

22. January 6, 1999 memo "Conjugated Estrogen Nomenclature" from Complex Drug Substance Coordinating Committee/Conjugated Estrogens Working Group, through Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Director, Division of Reproductive and Urologic Drug Products, Food and Drug Administration

23. March 15, 1999 memo "Addendum to January 6, 1999, Conjugated Estrogens Nomenclature Memorandum" from Complex Drug Substance Coordinating Committee/Conjugated Estrogens Working Group, through Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Director, Division of Reproductive and Urologic Drug Products, Food and Drug Administration

24. ICH Guideline for Industry, *The Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions* (March, 1995)

25. Center for Drug Evaluation and Research, May 5, 1997 "Synthetic Conjugated Estrogens - Questions and Answers"

26. Food and Drug Administration Guidance, *Guidelines for Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis* (April, 1994)

27. Stern, M.D., "Pharmacology of Conjugated Estrogens," *Maturitas*, 4:285-290, 1982.

28. Westerholm, B., "Clinical Toxicology of Estrogens," *Pharmacol. Ther.,* 10:337-349, 1980.

29. Hart, J.E., "Endocrine Pathology of Estrogens: Species Differences," *Pharmacol. Ther.*, 14:203-218, 1990.

30. IARC, "Some Hormones, Postmenopausal Hormone Therapy and Hormonal Contraception," *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans* 72:in preparation, June 2 – 9, 1998. Available on the IARC website at http:// 193.51164.11/htdocs/announcements/vol.72.htm

31. Li J.J., S.A. Li, J.K. Klicka, J.A. Parsons and L.K.T. Lam, "Relative Carcinogenic Activity of Various Synthetic and Natural Estrogens in the Syrian Hamster Kidney," *Cancer Research*, 43:5200-5205, 1983.

32. Li J.J., S.A. Li, T.D. Oberley and J.A. Parsons, "Carcinogenic Activities of Various Steroidal and Nonsteroidal Estrogens in the Hamster Kidney: Relation to Hormonal Activity and Cell Proliferation," *Cancer Research*, 55:4347-4351, 1995.

33. Food and Drug Administration Guidance for Industry, *Labeling Guidance for Non-Contraceptive Estrogen Drug Products – Physician and Patient Labeling* (1992)

34. Food and Drug Administration Draft Guidance for Industry, *Labeling Guidance for Non-Contraceptive Estrogen Drug Products – Physician and Patient Labeling* (1998)

35. CDER/CBER Guidance, *Guidance for Industry – Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* (May, 1998)

36. NDA #20-992 Approval Package - Cenestin (Synthetic Conjugated Estrogens, A) Tablets (to be redacted)